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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,884	07/10/2003	Brian M. Hatcher	10856 (UFL0009US2)	2636

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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
09/25/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/616,884	HATCHER ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-39 and 41-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-39 and 41-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/6/09 has been entered.

Claim Objections

Claim 43 is objected to because of the following informalities: The word "aluminates" is misspelled as *alurinates*. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11, 13, 21-25, 28, 30, 34, 36, 37, 39, 41, 42 and 44 are rejected under 35 U.S.C. 102(a) as being anticipated by Ducheyne et al (USPN 6,328,990 hereafter '990).

The '990 patent teaches a bioactive glass composite comprising at least one biocompatible polymer and a bioglass (abstract). The biocompatible polymer comprises poly(lactic co-glycolic acid) and polyvinyl alcohol (col. 3, lin. 35-44, claim 1). The bioglass includes at least one calcium molecule and at least one phosphorous molecule in an amorphous

form (col. 3, lin. 1-20). The composite is in the form of microspheres (claims). The microspheres include drugs (claims 7-10). The composites are used as a scaffold for tissue engineering and implantation (col. 6, lin. 5-53). The immersion process forms an amorphous glass material support matrix. The composite is formed by mixing the polylactic acid, with the glass component comprising at least one calcium molecule, one phosphorous molecule and an inorganic gelled alkoxysilane (col. 2, lin. 55-57). The mixture further comprises polyvinyl alcohol and is hydrolyzed (col. 3, lin. 35-45). This all occurs at room temperature far below 200 degrees Celsius (***Ibid.***). The microspheres can both encapsulate an active agent or act as a substrate for agents (col. 6, lin. 10-30). These disclosures render the claims anticipated.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17, 28-32, 34, 35, 36, 38, and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Marcolongo et al (USPN 5,721,049 hereafter '049).

The '049 patent teaches a composite material comprising bioactive glass in the form of fibers (abstract). The composite comprises a biocompatible polymer such as a polysulfone (Example III). The bioactive glass comprises at least on calcium molecule and at least one phosphorous molecule, as well as a gellable alkoxysilane (Example I). The glass can further included adjuster compounds such as minor amounts of an aluminum compound (Table I and II). The glass is extruded at high temperature resulting in an amorphous glass material (col. 5, lin. 35-50). The process forms fibers that are 50 microns in diameter (col. 7, lin. 5-15, claim 8) and useful for implantation (col. 13, lin. 5-10). The implants show excellent strength and tissue interaction with tissue in growth after several weeks without the aid of growth factors (col. 14,

lin. 23-47). The fibers can be arranged into an orderly support matrix; that is an interpenetrating fibrous network (Example II and III).

Regarding the composite at its ability to allow for the proliferation of stem cells, it is the position of the Examiner that these limitations are merely recitations of a future intended use. The claims recite that the "cells when seeded" will proliferate, meaning the composite is not yet seeded and as such any proliferation would be an inherent feature of the composite. The composite of the instant claims comprises a bioactive glass materials and biocompatible polymers, while the '049 patent teaches an identical composite. Since a compound and its properties cannot be separated, and the composite of the '049 patent is identical to that of the instant claims, it is the position of the Examiner that the composite of the '049 patent would also proliferate any seeded cells.

Regarding the claim limitation drawn to the biocompatible polymer reacting with the bioactive glass compound, it is the position of the Examiner that such a limitation does not differentiate the claims over the prior art. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In the instant case the instant claims are defined by a composite comprising a biocompatible polymer and a bioactive glass. The '049 patent teaches a composite material comprising a biocompatible polymer polysulfone and a

bioglass (comprising a calcium and phosphate molecular species). The '049 patent meets the structural limitations of the claims and thus anticipates the instant claims.

These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 13, 21-29, 34-39, 41, 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ducheyne et al (USPN 6,328,990 hereafter '990) in view of Ducheyne et al (USPN 5,591,453 hereafter '453).

As discussed above the '990 patent discloses a bioglass composite comprising bioglass and a biocompatible polymer. The reference discloses a biocompatible polymer combined with a bioactive glass component comprising at least one calcium molecule and at least one phosphorous molecule. Although the '990 patent discloses the inclusion of drugs, the reference

is silent to the specific proteins of the instant claims. The combination of specific proteins into a bioglass composite is well known in the art as seen in the '453 patent.

The ‘453 patent discloses a bioglass composite material and a method of incorporating biologically active molecules into the matrix (abstract). The bioglass comprises an inorganic alkoxysilane base material, tetramethylorthosilane, combined with a calcium molecule and a phosphorous molecule (col. 13, lin. 18-col. 15, lin. 16). The components are mixed and hydrolyzed forming particles (***Ibid.***). Biologically active molecules are incorporated in to the matrix including bone morphogenic protein (BMP) and platelet derived growth factor (PDGF) (col. 10, lin. 47-68). The composite can be used for implantation and to aid in repair of bone or other tissues, as a prosthetic device (col. 10, lin. 8-32). The porosity is controlled by the ratio of components. This porosity affects the sustained release of the biologically active molecules (col. 14, lin. 40-50). It would have been obvious to incorporate biologically active proteins as described by the ‘453 patent into the composite of the '990 patent in order to improve the bone and tissue growth of the patient after implantation.

With these things in mind it would have been obvious to combine the biologically active molecules of the ‘453 patent into the bioglass based composite of the '990 patent in order to increase the efficacy of tissue growth after implantation of the composite. This combination would have been obvious since both patents teach that active agents can be incorporated into bioglass based composites and used as implants for tissue repair, specifically bone repair. It would have been obvious to combine the prior art with an expected result of a bioglass based composite with sustained release of biological molecules that aid in and speed up tissue repair.

Claims 11, 12, 14, 18-20, 30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ducheyne et al (USPN 6,328,990 hereafter '990) in view of Shikinami (USPN 5,711,960 hereafter '960).

As discussed above the '990 patent discloses a bioglass composite comprising at least one calcium molecule and at least one phosphorous molecule, combined with a biocompatible polymer. The composite can be in the form of microspheres that are coated with a drug or can be coated to another substrate. The reference is silent to a specific fiber structure as the instant claims however this fiber structure is common in the art and the bioactive glass would have been an obvious addition to a fiber substrate structure in order to encourage tissue growth. This can be seen in the '960 patent.

The '960 patent discloses a biocompatible scaffold comprising a biocompatible polymer and bioactive glass on the surface of the fibers (abstract). The biocompatible polymers include polyethylene and poly-glycolic acid fibers (col. 10, lin. 50-61). Carriers for the scaffold include further biocompatible polymers such as cellulose gums and gelatin (col. 12, lin. 15-35). The bioactive glass is coated on the surface of the polymers (col. 18, lin. 29-42), and the bioactive glass polymers comprise calcium and phosphorous molecules (co. 17, lin. 45-col. 18, lin. 9). From the figures it is clear the scaffold in orderly with the fibers being placed evenly apart in order to create a scaffold configuration (Figures).The fiber scaffold has a void fraction (porosity) of 20-90% (claim 2). Though silent to specific number the fibers are arranged in an orderly fashion and appear to touch leaving the space between them less than 25 microns (Figures). It would have been obvious to coat the fibers of the '960 patent with the bioactive glass of the '990 patent in order to ensure increase tissue growth and reaction upon implantation.

Regarding the claim limitation drawn to the biocompatible polymer reacting with the bioactive glass compound, it is the position of the Examiner that such a limitation does not differentiate the claims over the prior art. The Patent Office bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. See *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. See *In re Marosi*, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir.1983). In the instant case, the prior art discloses a structurally complete composite that is identical to that of the instant claims. As discussed above the '990 patent discloses a composite material comprising a biocompatible polymer and a bioglass compound.

With these things in mind it would have been obvious to coat the fibers of the '960 patent with the bioactive glass of the '990 patent in order to increase the implants ability to react with surrounding tissue upon implantation, as well as encourage tissue in growth. The '960 patent teaches that the surface of the fiber mesh scaffold should be coated with bioactive glass for the expressed purpose of increasing tissue growth. The bioactive glass composite of the '990 patent accomplishes this end. It would have been obvious to combine the prior art in order to increase tissue growth at the implantation site. It would have been obvious to apply the fiber arrangement with an expected result of a stable implantable composite useful in bone repair treatments.

Response to Arguments

Applicant's arguments with respect to claims 11-39, and 41-44 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618